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10/789,246	02/27/2004	Jeffrey David Bettencourt	03-862-B	9463

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EXAMINER

CORDERO GARCIA, MARCELA M

ART UNIT	PAPER NUMBER
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1654

DATE MAILED: 01/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/789,246

Applicant(s)

BETTENCOURT ET AL.

Examiner

Marcela M. Cordero Garcia

Art Unit

1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 07 October 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) 12-16 and 18-24 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 17 is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)             | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

### **DETAILED ACTION**

Applicants' election with traverse of Group I, claims 1-19 in the reply filed on October 7, 2005 is acknowledged. The traversal is on the grounds that the groups would appear to at least overlap since both Groups I and II (claims 20-24) belong to the same class 530. As such, an examination of all the claims in a single application would not be unduly burdensome. Withdrawal of the restriction requested, therefore is in order and is earnestly solicited.

Applicants' arguments with respect to the restriction requirement have been carefully considered, yet not deemed persuasive for the reasons of record. The inventions of Group II and I are related as product and process of use, as it is of record. Classification within the same class does not constitute defining criteria for determining whether the search is co-extensive. As it is of record, the search for each of the inventions (Groups I-II) is not co-extensive particularly with regard to the literature search. Further, a reference which would anticipate the invention of one Group would not necessarily anticipate or even make obvious another Group. Finally, the consideration for patentability is different in each case. Thus, it would be an undue burden to examine all of the above inventions in one application.

The restriction requirement is still deemed proper and is therefore made FINAL.

With regards to the species election, Applicants' elect with traverse:

- (a) polyhistidine tagged cytokine as the species of tagged protein
- (b) heparin tagged support as the species of negatively-charged tagged support

(c) nickel nitrilotriacetic acid affinity support as the species of tag-specific affinity support.

Because applicant did not distinctly and specifically point out the supposed errors in the election of species requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 1-11 and 17 are readable on Applicant's elected species.

The species has been searched and found free of the prior art.

Examiner has therefore elected a new species from amongst those encompassed by the instant claims:

- (a) UPD-xylosyltransferase as the tagged protein
  - (b) heparin-agarose support as the negatively-charged tagged support
  - (c) Sepharose 6MB coupled to the dodecapeptide Q-E-E-E-G-S-G-G-G-Q-G-G
- as the tag-specific affinity support.

Claims 1-8 are readable on Examiner's elected species.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Pfeil et al. (Glycobiology, 2000).

Pfeil et al. teach a method for purifying a tagged protein (UPD-xylosyltransferase) from a protein preparation, comprising:

(a) concentrating the tagged protein in the protein preparation with a negatively charged capture support (heparin-agarose), comprising the steps of:

- (i) contacting the protein preparation with the capture support;
- (ii) washing the capture support with a capture support washing buffer of low ionic strength to remove interfering molecules but not the tagged protein from the capture support; and

- (iii) eluting the tagged protein from the capture support with a capture support eluting buffer of high ionic strength. (See, e.g., abstract; page 803, column 2, lines 36-43 and page 806, column 2, lines 11-19).

(b) purifying the tagged protein from the eluate of step (a) (iii) with a tag-specific affinity support comprising the steps of:

- (i) contacting the eluate of step (a) (iii) with the tag-specific affinity support;
- (ii) washing the affinity support with affinity support washing buffer of low ionic strength to remove some impurities but not the tagged protein from the affinity support; and
- (iii) eluting the tagged protein from the affinity support with an affinity support eluting buffer. (See, e.g., page 804, column 1, lines 4-26 and page 806, column 2, lines 11-19).

Therefore, the reference is deemed to anticipate the instant claims above.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pfeil et al. (Glycobiology, 2000).

Pfeil et al. beneficially teach a method for purifying a tagged protein (UPD-xylosyltransferase) from a protein preparation, comprising:

(a) concentrating the tagged protein in the protein preparation with a negatively charged capture support (heparin-agarose), comprising the steps of:

(i) contacting the protein preparation with the capture support;

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(ii) washing the capture support with a capture support washing buffer of low ionic strength to remove interfering molecules but not the tagged protein from the capture support; and

(iii) eluting the tagged protein from the capture support with a capture support eluting buffer of high ionic strength. (See, e.g., abstract; page 803, column 2, lines 36-43 and page 806, column 2, lines 11-19).

(b) purifying the tagged protein from the eluate of step (a) (iii) with a tag-specific affinity support comprising the steps of:

(i) contacting the eluate of step (a) (iii) with the tag-specific affinity support;

(ii) washing the affinity support with affinity support washing buffer of low ionic strength to remove some impurities but not the tagged protein from the affinity support; and

(iii) eluting the tagged protein from the affinity support with an affinity support eluting buffer. (See, e.g., page 804, column 1, lines 4-26 and page 806, column 2, lines 11-19).

Pfeil et al. does not expressly teach specific ionic strengths for the buffers.

It would have been obvious to one of ordinary skill in the art at the time the invention was made that if a buffer gradient will elute the protein then just switching to high ionic strength buffer would work as well.

Thus, the invention as a whole is prima facie obvious over the reference, especially in the absence of evidence to the contrary.

**Conclusion**

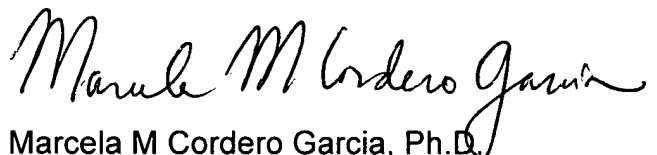
Claim 17 is allowed. Instant claims 1-11 would be allowed if claims were to be amended to only encompass Applicant's elected species.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marcela M. Cordero Garcia whose telephone number is (571) 272-2939. The examiner can normally be reached on M-Th 7:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on (571) 272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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MMCG 01/06



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